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Treatment of Intermittent Claudication: The Impact on Quality of Life

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Objectives: *To measure changes in claudicant's quality of life after surgery, angioplasty or unsupervised exercise. To explore the relationship between clinical indicators of limb perfusion and patient's perception of health change.*
Design: *Prospective study.*
Setting: *University Hospital vascular outpatients.*
Materials and Methods: *202 claudicants referred for Duplex of lower limb arterial disease over a 12 month period. The short form 36 questionnaire was used to determine quality of life. Ankle pressures and walking distances were determined.*
Main Results: *The SF-36 was completed by 186 patients (92%) before and after treatment (34 operative patients, 74 angioplasty and 78 treated by exercise alone). Baseline quality of life was worse in surgical patients. Unsupervised exercise produced minimal changes in quality of life. Angioplasty and operation produced similar, significant improvements in physical functioning and pain. Changes in physical function or pain scores were unrelated to changes in ankle pressure.*
Conclusions: *Unsupervised exercise programs are unlikely to significantly improve patient's quality of life. The benefits of surgery and angioplasty support a relaxation in the indications for investigation and treatment of claudicants. Patients with impaired perceived health should not be denied treatment on the basis of preintervention ankle pressure or walking distance alone.*

Key Words: Quality of life; Claudication

Introduction

Traditionally, patients with mild claudication, are treated conservatively.[1] The risk of amputation (1.5–5% over 5 years) is overshadowed by the increased mortality in these patients.[2,3] Structured exercise programs may improve walking distances and modification of risk factors, particularly cessation of smoking, is widely advocated.[1,4,5]

The proportion of claudicants treated by operations and angioplasty is rising, indicating an expansion in the indications for investigation and treatment.[6] With the development of non-invasive vascular assessment, this trend may accelerate.

Mortality, morbidity and objective indicators of limb perfusion (ankle pressure and treadmill walking distance) are established outcome measures after treatment of claudication. The primary aim of treatment is symptomatic improvement and an enhanced prognosis for life and limb. The impact of treatment on patient's quality of life is essential yet has not been measured.

The aim of this study was to assess the impact of an exercise program, angioplasty and surgery on the quality of life of claudicants. The association between changes in ankle pressure, pre-intervention claudication distance and patient's perception of health change was also explored.

Patients and Methods

Patients

Two hundred and two claudicants, referred for lower limb arterial Duplex between April 1993 and March 1994, completed a quality of life assessment at the time of non-invasive investigation. Patients were referred from vascular outpatient clinics for investigation of lower limb arterial occlusive disease. During this 12 month period, 315 patients underwent lower limb duplex for peripheral vascular disease. Duplex was

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only performed in patients thought potentially suitable for vascular intervention. Resting ankle pressures were measured using the Doppler method and following exercise on a treadmill. Subsequently, patients underwent vascular operations, percutaneous transluminal angioplasty (PTA) or were treated conservatively. The latter consisted of a daily exercise program designed by the physiotherapy department and based on a previous, hospital-based exercise program.[7]

Patients were recalled for review in the clinic or vascular studies unit, 3 months after the initial quality of life assessment. Patients initially unable to attend were sent repeat appointments. The quality of life questionnaire was repeated and ankle pressures at rest determined as before.

Quality of life questionnaire

The anglicised version of the SF-36 quality of life questionnaire was used to determine pre- and post-intervention quality of life. This generic questionnaire is sensitive to changes in quality of life and is validated for use in a British population.[8] The self administered questionnaire contains 35 items used to measure the following 8 multi-item dimensions of quality of life: (1) physical functioning (Phys Fun), (2) social functioning (Soc Fun), (3) role limitations due to physical problems (Phys Role), (4) role limitations due to emotional problems (Em Role), (5) pain, (6) mental health (MH), (7) vitality (Vit) and (8) general health perceptions (GHP). An additional item, addressing health change, is recorded but not scored. For each dimension, item scores are coded, summed and transformed to produce a score ranging from 0% (worse quality of life) to 100% (best possible quality of life measured by the questionnaire).[9]

Statistical Analysis

Quality of life dimension scores did not follow a normal distribution (Kolmogorov-Smirnov goodness of fit test[10]). The change in quality of life after surgery, angioplasty or the exercise program was assessed by the Wilcoxen matched pairs signed ranks test. The change in quality of life was also expressed as the effect size for each health dimension in the three patient groups, calculated as: the mean postintervention score minus the mean preintervention score divided by the S.D. of the preintervention mean. Effect size enables health changes in different populations to be compared.[11,12] Differences in the changes in health dimension scores between the three patient groups were assessed by the Mann-Whitney U-test. Changes in eight health dimensions were assessed, thus values significant at the 0.05 level, but not the 0.01 level, should be treated with caution.

It was hoped that treatment would show a maximum change in physical functioning and pain dimensions. The changes in these aspects of quality of life were compared to changes in ankle brachial pressure indices (ABPI) by Spearman's rank correlation test. Changes in physical functioning and pain dimensions were calculated for males and females, and those aged over and less than 65 years. The differences in health change for age and sex were assessed by the Mann-Whitney U-test. Patients were grouped according to their preintervention walking distance into <100 yards, 100 to 200 yards and >200 yard groups. Difference in changes in physical function and pain between these three groups was tested by Kruskal-Wallis one way analysis of variance.

Results

Of the initial 202 patients, 186 (92%) completed a follow-up questionnaire. Four patients died after their initial assessment, three were unable to complete the follow-up questionnaire and nine were lost to follow-up. One hundred and sixty of the follow-up questionnaires were fully completed, the remainder had missing information, usually in only one health dimension. Quality of life was thus assessed before and after 34 vascular operations, 74 angioplasties and 78 patients treated by an exercise program (Table 1). The vascular operations and angioplasty sites are shown in Table 2 (some patients underwent angioplasty to more than one site).

The preintervention quality of life scores of four health dimensions is shown in Fig. 1. There were no significant differences between the three patient groups in mental health, emotional role, vitality and

Table 1. Patients assessed before and after intervention

	Operation	PTA	Exc
Number	34	74	78
Females (%)	11 (32%)	21 (28%)	19 (24%)
Median age (range)	67 (44–82)	73 (44–82)	68 (37–93)
Mean ABPI	0.64	0.7	0.65
Diabetics (%)	7 (21%)	10 (14%)	8 (10%)
Cardiac symptoms (%)	11 (32%)	22 (30%)	32 (41%)

Exc = Exercise program only.

Table 2. Operations and Angioplasties

Operations	Number	PTA	Number
Aortic aneurysm	1	Iliac	31
Aorto bifemoral	7	Common femoral	4
Iliofemoral	1	Superficial femoral	41
FFXO	2	Popliteal	9
CFA EA	6		
Femoral aneurysm	1		
Femoropopliteal	15		
Amputation	1		

FFXO = femorofemoral cross over, CFA EA = common femoral endarterectomy.

general health perception. The preintervention scores for physical functioning, physical role problems, social functioning and pain were worse in the operative group compared to both the angioplasty and exercise groups.

The changes in four health dimensions for the three patient groups are shown in Table 3. In addition, general health perception showed an improvement in patients undergoing angioplasty and operation ($p < 0.05$), mental health improved in the angioplasty group ($p0.05$) and social function improved in the operative group only ($p < 0.05$ Wilcoxen matched pairs signed ranks test). The changes in health are expressed as an effect size in Fig.2.

The mean change in ABPI was –0.014 for the exercise group and 0.113 for the PTA group ($p < 0.0001$ unpaired t-test). The operative group had a mean change in ABPI of 0.324, significantly greater than the angioplasty patients ($p < 0.0001$ unpaired t-test). The change in mean ABPI for each patient showed no significant relationship with changes in any of the eight health dimensions. The strongest association was between the maximum change in ABPI and changes in physical functioning (r = 0.339). Patients aged more than 65 years and female patients had a marginally poorer improvement in physical functioning and pain compared to young, male patients although the differences were not significant.

Preoperative walking distance had no significant influence on the change in physical function or pain as shown in Table 4. Fifty-nine patients (three operative, 38 PTA, 18 exercise) with preintervention walking distances, equal to or greater than 200 yards had a mean change in physical function of 12.33% (median 10%, effect size 0.67 S.D.) and change in pain score of 11.73% (median 10% effect size 0.62 S.D.).

Discussion

A validated questionnaire, sensitive to potentially small changes in health and easy to use yet providing a comprehensive assessment of quality of life was required. Most patients completed the SF-36 within 10 min without difficulty. Failure to fully complete the SF-36 was more common in elderly patients, as previously reported.[8] However, acceptable results were obtained in those aged over 65. The poorer response of the elderly and female patients to treatment is consistent with previously reported lower population norms for these patients.[13] As follow up was combined with reassessment in the clinic or vascular studies unit, the response rate was high. The questionnaire was sensitive to health changes in claudicants and demonstrated the expected improvement in pain and physical function scores, providing

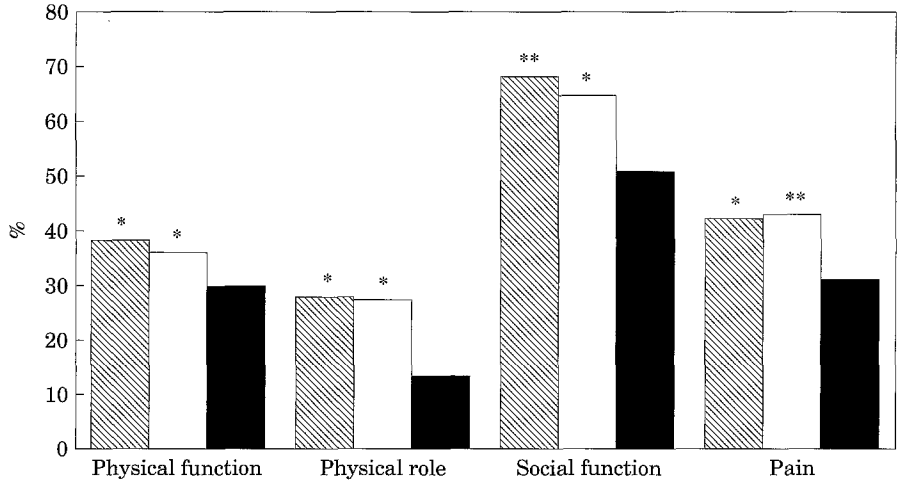

Fig. 1. Pre-intervention quality of life profile. (▨)PTA; (□) exercise; (■) operation; *$p < 0.05$; **$p < 0.01$, Mann-Whitney U-test (significantly higher than operation group.

Table 3. Change in quality of life

	Physical functioning			Physical role			Pain			Vitality		
	PTA	Exercise	Operation	PTA	Exercise	Operation	PTA	Exercise	Operation	PTA	Exercise	Operation
Mean % change	18	3	18	19	5	16	17	7	17	8	3	9
Median % change	20	0	15	0	0	0	11	1	19	5	0	15
Upper 95% limit	24	6	26	30	12	30	24	11	27	12	7	17
Lower 95% limit	12	0	9	8	–3	1	11	2	6	4	–1	2
$p<$	0.001	0.2	0.002	0.005	0.25	0.05	0.001	0.005	0.01	0.05	0.1	0.05

good evidence for its construct validity.[11] Ceiling and floor effects (the inability to measure changes in previously good or poor levels of health) did not occur in the population studied.

The policy of our unit is to screen claudicants by Duplex prior to arteriography. The patients studied were thus representative of those with mild to moderate symptoms. Pain and limitations in physical and social functioning appear strong factors in the decision to operate whereas preoperative ABPI were similar in the three groups. Cardiac symptoms were more common in patients treated by exercise, perhaps indicating a reluctance to submit these patients to surgery.

The exercise program produced little change in quality of life with only a slight improvement in pain score. In contrast, the potential of a structured exercise program to improve walking distance (but with little effect on ankle pressure) is well established.[4,7,14] The long term effects of such a program, after cessation of the exercise class, are not known although Creasy demonstrated a continued improvement in walking distance 9 months after the end of the program.[4] Structured hospital-based exercise programs place demands on staff and patient time which should be demonstrated to produce significant improvement in patient's quality of life before their introduction. Thus, such programs are not in widespread use in this country. Recent concern over the systemic effect of the transient muscle ischaemia, produced by claudication, may strengthen the conclusion that exercise therapy is of unproven long term benefit to patient's quality of life.[15,16]

Improvement in physical functioning and pain were similar for angioplasty and operative patients despite a significantly larger improvement in ABPI in the operative group. The cost to the patient and hospital of bypass surgery exceeds that of angioplasty.[17] Our

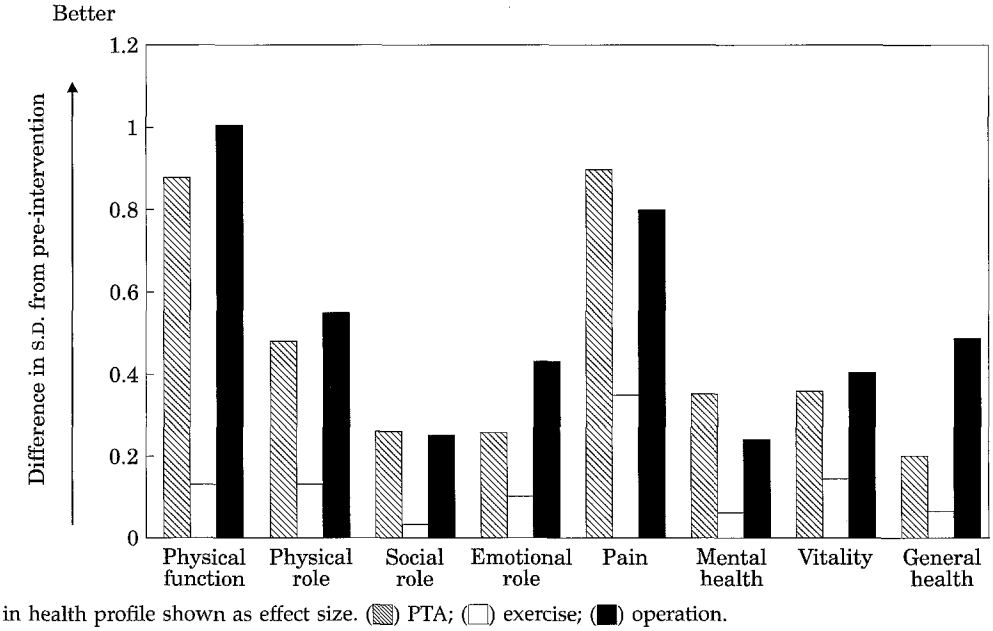

Fig. 2. Changes in health profile shown as effect size. (▨) PTA; (□) exercise; (■) operation.

Table 4. Pre-intervention walking distance and changes in pair and physical function

	Mean change physical function (%)	Mean change pain (%)
Walking distance (yds)		
<100	14	11
100–200	11	15
>200	17	12

No significant differences for pain or physical funtion, Kruskal-Wallis $p > 0.4$.

policy is to offer angioplasty as the treatment of first choice for claudication, most patients that progress to surgery have disabling symptoms and lesions unsuitable for endoluminal therapy.

Improvement in ankle pressure has been an important indicator of the success of revascularisation procedures, yet it shows only a weak correlation with changes in quality of life. Improvement in treadmill walking distances may produce a closer correlation with quality of life changes although this was not assessed. Preintervention walking distance failed to predict improvement in physical functioning and pain scores. Patients with mild claudication ($\geq$200 yards) obtained a significant improvement in physical function and pain, due largely to the benefits of angioplasty. Many claudicants with walking distances over 200 yards had single, focal lesions ideal for angioplasty. Effect size enables comparison of health change across different group of patients with varying health conditions using generic questionnaires.[11,12] To date, few studies have reported effect size changes in the SF-36 following surgical treatments. In clinical terms, an effect size of 0.2 represents a slight change in health, 0.5 is moderate and >0.8 a large change in health.[12] Baker *et al.* assessed varicose vein surgery using the SF-36 and reported the effect size for physical function and pain to be approximately 0.4 S.D.[18] This is less than half the effect size achieved by angioplasty and operation in this study. The implications of this type of comparison, in a climate where providers are increasingly under pressure to demonstrate the benefits of the treatments they offer, are important.

Conclusions

Unstructured exercise treatment of claudication had little impact on patient's quality of life. Structured hospital based exercise programs should be shown to provide a significant improvement in patient's health perception if the demands on staff and patients of this form of treatment are to be justified.

Angioplasty and surgery both provide similar, improvements in quality of life. In the assessment of patients with claudication, the morbidity and mortality of the treatment should be balanced against the potential benefits in quality of life. On the basis of these findings, claudicants with impaired health perception may derive a significant benefit from revascularisation procedures and cannot be denied treatment on the basis of walking distance or ankle pressure alone. Patients with mild claudication are likely to have focal lesions eminently suitable for dilatation. The potential to extend the benefits of angioplasty to those with mild claudication, compared to traditional, conservative management, deserves further assessment.

Postoperatively we hope the patient reflects; "That was rough but worth it — it has made a big difference to my life."[1] This study quantifies this difference in quality of life for operative, angioplasty and exercise therapy in claudicants.

Acknowledgements

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